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09/972,794	10/05/2001	Andrea Amalfitano	5405-232DV	5221

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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/972,794

Applicant(s)

AMALFITANO ET AL.

Examiner

Dave T. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 44, 50, 52, 54, 55 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 13, 15, 16, 25-41, 59-70, 75, 94-98, 105-109, 111-116, 132, 133, 146-148 and 207-222 is/are allowed.
- 6) ☐ Claim(s) 80, 83 and 84 is/are rejected.
- 7) ☐ Claim(s) 81, 85 and 86 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 1-5,13,15,16,25-41,44,50,52,54,55,59-70,75,80-86,94-98,105-109,111-116,132,133,146-148 and 207-222.

Continuation of Disposition of Claims: Claims allowed are 1-5,13,15,16,25-41,59-70,75,80-86,94-98,105-109,111-116,132,133,146-148 and 207-222.

Claims 6-12, 14, 17-24, 42-43, 45-49, 51, 53, 56-58, 71-74, 76-79, 87-93, 99-104, 110, 117-131, 134-145, and 223-236 have been canceled, examined claims 1-5, 13, 15, 16, 25-41, 59-70, 75, 80-81, 83, 85-86, 94-95, 105, 107-108, 111-113, 115, 133, 146, 207-209, and 219 have been amended, and withdrawn claims 44, 50, 52, 54, 55, 60-62, 109, and 210-212 have been amended by the amendment dated October 14, 2003.

Applicant's request to rejoin claims 63-65 to the examined claims is found persuasive, and thus, claims 63-65 have been rejoined to the examined claims. In addition, claim 68 should have been withdrawn from the examined claims in the first office action, and thus, is now withdrawn from examination.

However, given that linking claims 59, 105, and 207 are in condition for allowance, amended withdrawn claims 60-62, 68, 109, 210-212 have been rejoined to the allowed base claims and claims dependent there from.

Thus, only claims 44, 50, 52, 54, 55 have been withdrawn from examination as non-elected claims.

Claims 1-5, 13, 15, 16, 25-41, 59-70, 75, 80-86, 94-98, 105-109, 111-116, 132-133, 146-148, and 207-222, of which claims 1-5, 13, 15, 16, 25-41, 59-70, 75, 94-98, 105-109, 111-116, 132-133, 146-148, and 207-222 are in condition for allowance, are pending for examination.

Pending and examined claims 80-86 remain subject to the following objection and rejection.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

a person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 80, 83 are rejected under 35 U.S.C. 102(e) as being anticipated by Reddy *et al.* (US 6,492,343).

Reddy teaches an isolated or cultured porcine cell comprising an isolated DNA sequence comprising PAV-3 left and right ITR(s), packaging signal sequence, and encodes a functional PAV-3 100K protein (entire disclosure, especially column 11 through column 12.

Thus, the patent anticipates the claims.

Claims 80, 82-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slemenda (Nucleic acids Res, Vol. 18, No. 10, 1990) taken with Oosterom-Dragon (J. of Virology, Vol. 33, No. 3, pp. 1203-1207, 1980) and Reddy (US 6,492,343).

Slemenda teaches an isolated DNA encoding a 100K protein of human enteric adenovirus type 41 (Tak) (entire disclosure). Slemenda does not teach that the DNA can be used for production of 100K proteins and subsequent immunological characterization.

However, at the time the invention was made, Oosterom-Dragon teaches that Ad 100K proteins are essential for the production of Ad hexons and a desire to determine its immunological characteristics.

In addition, Reddy teaches that DNA recombinant techniques such as those mammalian cell production system, as disclosed in the prior art cited on column 7 and column 8, are well-established in the prior art of record.

It would have been obvious for one of ordinary skill in the art to have employed the DNA recombinant techniques available in the prior art to produce 100K proteins by using the isolated DNA of Slemenda in any cell-expression systems including a

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eukaryotic cell production systems known in the prior art, *e.g.*, K-16 or C7 cells. One would have been motivated to use the isolated DNA coding for 100K protein of human enteric adenovirus type 41 (Tak) in a cell production system such as those described on columns 7 and 8 of Reddy or any equivalent cell line known in the prior art, because Oosterom-Dragon teaches that Ad 100K proteins are essential for the production of Ad hexons and that there is a desire to determine the immunological characteristics of any isolated Ad 100K gene.

Thus, the claimed invention as a whole, was *prima facie* obvious.

Applicant's response, pages 24-25, has been considered by the examiner, but is not found persuasive because of the reasons set forth in the stated rejection.

More specifically, Applicant mainly asserts that in view of the functional limitation cited in the claim, the claims are neither anticipated nor obvious. In response, the examiner maintains that the main thrust of the invention is that as long as an isolated mammalian cell has a production system such as a promoter operatively associated with an Ad 100K protein encoding sequence, the cell is capable of propagate an adenovirus genome as claimed. The claims when read in light of the specification is not limited *per se* to any particular mammalian cell that would distinguish applicant's claims from Ad-100 protein expressing mammalian cells known in the prior art. As such, an old composition claim which is written to recite a newly found property is not patentable, particularly in view of the reasons set forth in the stated rejection.

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Claims 81, 85, 86 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Clark*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

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Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
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DAVE T. NGUYEN
PRIMARY EXAMINER